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<p>(21) International Application Number: PCT/US98/16250</p> <p>(22) International Filing Date: 4 August 1998 (04.08.98)</p> <p>(30) Priority Data: 60/054,622 4 August 1997 (04.08.97) US</p> <p>(71) Applicant (for all designated States except US): GORDON, MAYA, ROBERTS & THOMAS NUMBER 1 LLC [US/US]; 2115 Thiel Avenue, McKinleyville, CA 95519 (US).</p> <p>(72) Inventor; and</p> <p>(75) Inventor/Applicant (for US only): GORDON, Dennis, P. [US/US]; 1244 Rancho Circle, Las Vegas, NV 89107 (US).</p> <p>(74) Agent: DALY, Thomas, J.; Christie, Parker & Hale, LLP, P.O. Box 7068, Pasadena, CA 91109-7068 (US).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published With international search report.</p>	
<p>(54) Title: MULTIPLE AXIS INTERVERTEBRAL PROSTHESIS</p> <p>(57) Abstract</p> <p>The present invention relates to an intervertebral prosthetic disk. The prosthesis comprises a male component (10) with a support plate (18), an attachment element (16) allowing fixation to a vertebra, an articulating projection (60), and a female component (12) with a support plate (50), an attachment element (16) allowing fixation to a vertebra, and a circular procket (54) with angled walls (56) suitable for receiving the articulating projection. The male component is placed inside the female component. The two components are attached to the adjacent vertebrae, and act as a replacement for a disk. The prosthesis allows for a natural range of motion for the patient.</p>			

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MULTIPLE AXIS INTERVERTEBRAL PROSTHESIS

5 BACKGROUND OF THE INVENTION

This application is a regular utility patent application claiming the priority of U.S. Provisional patent application number 60/054,622, filed August 4, 1997.

FIELD OF THE INVENTION

10 The present invention relates to an intervertebral prosthesis, for the replacement of multiply-operated or degenerative disks that are creating painful motion or nerve root compression. In particular, this invention relates to a prosthesis with two components, able to rotate inside the other, while each is fixed to its adjacent vertebra.

15 BACKGROUND OF THE INVENTION

Disk disease is endemic. When a spinal disk in a patient is no longer serviceable, a fusion is often done. A fusion involves the removal of the degenerative vertebral disk, which had allowed for movement and rotation of the adjacent vertebrae relative to one another. The two vertebrae surrounding the disk are then joined and fixed, removing the mobility from that area. 20 However, fusions have many disadvantages. They are destructive and have a significant failure rate. They encourage degenerative disease of the disks above and below and most often require donor bone, which causes its own set of complications.

25 The evolution of surgical treatment of other diseased joints has progressed from fusion, to debridement and resurfacing and then to joint replacement. The standard of care for surgical treatment of advanced disease of hip and knee joints is now joint replacement. However, the search for a working spinal disk replacement has not yielded as great of a success as of yet. The currently available experimental prostheses are not widely accepted.

30 There are a number of ball and socket type arrangements that have been developed for disk prostheses, but the problem with existing prostheses is that none of the devices address the need for self centering of the ball within the socket. Self-centering is an important feature because it allows the prosthesis to imitate the normal motion of the disk. The availability of a mechanism which enables a ball and socket type prosthesis to self-center would give a patient a flexible, natural-feeling prosthesis. An additional problem which is not addressed by the existing devices is any sort of specific method for building lordosis into the prosthesis. The 35 advantage of building lordosis into the prosthesis is that it allows the back to have a more natural curvature, rather than an artificial stiffness. For a disk prosthesis to be as successful as some other joint replacements, it needs to allow for as much natural movement as possible.

5 It is also important that a prosthesis allows the anatomy of the motion segment to be the constraining factor for the limits of motion. If the prosthesis is intrinsically constrained, then it must bear the stresses of constraint, particularly at the bone/prosthesis interface, as well as internally in the prosthesis. Other fully constrained prostheses, such as total knees or elbows, have failed. If a prosthesis was developed that allowed the anatomy of the motion segment to be the constraining factor, then the facets and soft tissue would bear the stresses of constraint allowing for longer life of the prosthesis. The life of the prosthesis should be long enough to
10 make the operation worthwhile, so it need not be repetitive.

It is desirable that a prosthesis be provided that allows for a significant range of motion, that mimics the motion of an actual vertebral disk. Ideally, it would be stable, without intrinsic constraining factors, but not stiff, so it will have a long lifetime, and feel as natural as possible.

15 **SUMMARY OF THE INVENTION**

Therefore, the present invention provides for an intervertebral prosthesis that self-centers, allows a range of motion, and in a preferred embodiment also provides for lordosis considerations. The prosthesis is designed to alleviate a painful motion segment, for degenerative disk disease, for the multiply operated disk, or to relieve nerve root compression.

20 The prosthesis assembly comprises a male component which can rest in the female component, while both are attached to adjacent vertebrae. The male component consists of a support plate, preferably wedge shaped, from which, in a particularly preferred embodiment, one flange extends. The flange is preferably defined as a mounting tab that extends vertically from the edge of the component. It contains at least one hole through which an attachment element, such as preferably a screw, may pass, for fixation to adjacent vertebrae. The hole may be
25 preferably in the shape of a figure eight. The preferred means for attachment to the adjacent vertebra is screws which pass through holes in the flange. The male component also consists of an articulating projection, which is preferably doughnut shaped. When assembled with the female portion, it allows for multiple axes of rotation. The doughnut shaped projection preferably contains a double radius for ease in self-centering.

30 The female component consists of a support plate, preferably flat, from which, in a preferred embodiment, one flange extends vertically. The preferred means for attaching the female portion to the adjacent vertebra is screws which pass through holes in the flange. The female component also comprises a circular pocket with angled walls in which the male component can rest. In another preferred embodiment, the female component has a coating or insert on the inside surface of the pocket to reduce friction between the components. Preferably, the material for the coating is plastic or ceramic.

5 In a preferred embodiment, the system comprises a porous coating, on the bone-facing surfaces of the support plates, to allow for a second method of fixation to the vertebra. The components may preferably be made of a metal alloy or of a ceramic material. The two components can also be made of dissimilar materials from each other. A particularly preferred prosthesis conforming to the present invention is made of chromium cobalt alloy to give strength and longevity to the prosthesis.

10 BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the invention will be more fully understood when considered with respect to the following detailed description, claims and accompanying drawings where:

15 FIG. 1 is a perspective view of an intervertebral prosthesis, according to the present invention with the two components placed together;

FIG. 2 is a top view of the female component of the intervertebral prosthesis of FIG.1;

FIG. 3 is a perspective view of a flange portion of the intervertebral prosthesis of FIG.1 with figure-eight shaped attachment openings;

20 FIG. 4 is a side view, partly in section, of the male component and the female component of the intervertebral prosthesis of FIG.1 spaced apart from one another; and

FIG. 5 is a perspective view of an alternate embodiment showing a double flange with an angled screw.

DETAILED DESCRIPTION

25 The present invention relates to a variable axis intervertebral disk prosthesis (see FIG. 1). The prosthesis has two components (see FIG. 4), male 10 and female 12, and is for implantation between two adjacent vertebrae in place of a spinal disk. Attachment to the adjacent vertebrae is accomplished at least in part by means of an attachment element, preferably mechanical attachment elements such as screws 14 which pass through a flange 16. Alternatives to screws 30 such as pegs or posts are acceptable means for attaching the components to the vertebrae, as long as they are strong enough to handle the compressive forces exerted on it, and are a reliable form of fixation. Bone cement may also be used for attachment to the adjacent vertebrae, either in place of or in addition to mechanical attachment elements. The preferred length and diameter of the mechanical attachment elements is determined by the surgeon depending on the size of 35 the patient and the location in the spine where the disk is being replaced. If using screws, they may be inserted straight into the vertebrae or at an angle. In one preferred embodiment, the screws are inserted straight into the vertebrae (see FIG.1). In another preferred embodiment, a screw is inserted into the vertebra at an angle (see FIG. 5).

5 The male portion 10 of the prosthesis comprises a cylindrical support plate 18, which in a preferred embodiment is wedge-shaped. The wedge-shaped plate 18 allows for building lordosis into the prosthesis. The wedge-shaped plate 18 has one rough-faced surface 20 that would mate with a vertebra. In a preferred embodiment, the male component 10 is the upper component and the rough surface 20 is on the upper surface 80 of the wedge-shaped plate 18 (see FIG. 4). The rough surface allows for another means of fixation to a vertebra, as an alternative to or in addition to the mechanical attachment elements. A presently preferred embodiment has 10 both attachment elements, such as screws 14, and a rough surface 20 to provide for the most stable fixation.

15 Extending vertically from the edge of the upper surface 20 of the support plate is at least one flange 16. In a preferred embodiment, the male component is the upper component and the flange extends upward from the thick side of the wedge-shaped plate 28 (see FIG. 1). The flange is a mounting tab that can receive the attachment elements, such as screws 14. The screws are guided through openings 22 in the flange in order to attach the male portion 10 to a vertebra. There are at least two openings 22 through which (at least two) attachment elements can pass. In a preferred embodiment, the openings 22 in the flange 16 are figure eight shaped openings 34 (see FIG. 3). The figure eight shaped opening aids in facilitating different screw heights. 20 Different heights are chosen by the surgeon depending on what best fits each particular patient. The opening 22 can also be circular, or oval in shape.

25 The openings can also have a wider mouth section at their outer edge (see FIG. 2) to accept the heads of screws placed through the openings. For ease in seeing the mouth sections, the screws in FIG. 1 are backed slightly out of the openings. However, when fully inserted, the heads of the screws would be at least partly received within the mouth sections to present a smoother outer surface for the flange, thereby causing less irritation to overlying tissue.

 In another embodiment, there are two flanges 70 extending vertically from the plate (see FIG. 5). Each flange has at least one opening 22 for an attachment element to pass through.

30 In an alternative embodiment, the male component has an additional opening 24 for attachment to a vertebra (see FIG. 5). This opening 24 extends from the lower edge of the cylindrical wedge 26 on the male portion 10 at the thick side of the wedge 28. The opening 24 is angled so that an attachment element, such as a screw 74, can be inserted into the vertebra through the opening 24 at an angle. The opening is also recessed at the lower end 36, to receive the head of a screw 30 which is at an angle.

35 The male component further comprises a projection with an articulating surface 60. This projection has rounded edges 58 and extends downward from the lower surface of the wedge-shaped plate 42. The preferred embodiment consists of a projection which is doughnut shaped 60, with a smaller neck 62 containing one radius, and a bulging protrusion 64 containing another

radius. The doughnut shaped projection allows for range of motion. When the prosthesis is assembled, the projection 60 will then rest inside the female portion 12.

5 Alternatively, the projection on the male component can have straight cylindrical side walls with a rounded top (see FIG. 5). As with the previously described embodiment, the top of the projection will have a radius such that it will rest inside the female portion and allow for a range of motion.

10 The female portion 12 of the prosthesis comprises a cylindrical support plate 50, which is preferably flat. The plate 50 preferably has one rough-faced surface 44 that would mate with a vertebra. In a preferred embodiment, the female component is the lower component (see FIG.1), and the rough surface 44 is on the lower surface of the support plate 78. The rough surface allows for another means of fixation to a vertebra, as an alternative to or in addition to the mechanical attachment elements. A presently preferred embodiment has both attachment 15 elements, such as screws 14, and a rough surface 44 to provide for the most stable fixation.

20 The female component has at least one flange 16 extending vertically from the edge of the support plate. In a particularly preferred embodiment, the female component is the lower component and the flange extends downward from the edge of the lower surface of the support plate 78 (see FIG.1). The flange is a mounting tab that can receive attachment elements, such as screws 14. The screws are guided through openings 22 in the flange in order to attach 25 the female portion 12 to a vertebra. There are at least two openings through which at least two attachment elements can pass. In a preferred embodiment the openings 22 in the flange 16 are figure eight shaped openings 34 and have mouth sections (see FIG.3). The figure eight shaped opening aids in facilitating different screw heights. The opening 22 can also be circular, or oval in shape.

In an alternative embodiment, there are two flanges 70 extending vertically from the plate (see FIG.5). Each flange has at least one opening 22 for an attachment element to pass through.

30 Also, the female component has an additional opening 46 for attachment to a vertebra (see FIG. 5). This opening 46 extends through the end of the flange nearest the plate 98. The opening 46 is angled so that an attachment element, such as a screw 74, can be inserted into the vertebra through the opening at an angle. The opening is also recessed at the lower end 76 to receive the head of the screw, which is at an angle.

35 The female component further comprises a cylindrical concavity in the form of a cup-shaped pocket 54. The cup-shaped pocket extends up from the upper surface of the flat plate 52. The cup-shaped opening 54 is adapted to receive the rounded projection of the male portion 60. The rounded edges 58 of the male projection rest inside the pocket of the female component. The pocket is designed with angled side walls 56. The angled side walls allow the male portion 10 to center itself within the pocket as the male portion 10 tilts in any direction.

5 In the preferred embodiments shown, the angled side walls 56 are straight. It is particularly preferred to have the angled side walls be substantially straight so that the rounded male projection can easily slide within the cup-shaped opening to center itself. However, the angled side walls could be somewhat inwardly curving or concave without having a substantial adverse impact on centering. What is important is that the angled side walls, if they are curved, have a radius of curvature significantly larger than that of the rounded male projection where it contacts the side walls.

10 In an alternative embodiment, the side walls 56 are coated with or have overlying them an insert of a material that helps reduce friction between the two components. The coating or insert can be made of plastic or ceramic.

15 In the preferred embodiments, when the two components 10,12 are placed together (see FIG. 1) the rounded projection 60 of the male component 10 fits into the cup shaped pocket 54 of the female component 12. The male component 10 then lies partly in the cylindrical pocket. As the male component goes through ranges of motion, the angled walls 56 of the female component 12 center the male component with the female component. The ranges of motion allowed around a spinal disk by human anatomy are approximately 15 degrees of flexion, 5 degrees of extension, 1 degree of rotation and 5 degrees of lateral bending. The prosthesis of the 20 present invention is capable of those ranges of motion or more. For example, the prosthesis is capable of an unlimited range of rotation. Thus, the prosthesis is capable of an unlimited range of rotation. Thus, the prosthesis is capable of the normal range of motion and it should be the anatomy of the motion segment itself that imposes constraints on ranges of motion.

25 The components 10,12 of the system are preferably made of a metal alloy or ceramic material which is physiologically compatible with the vertebrae. The two components can also be made of dissimilar materials from each other. However, metal to metal contact allows for strength in the prosthesis. A particularly preferred embodiment is made from chromium cobalt alloy, but one skilled in the art would realize other possible materials or composites could be used that would be adequate to provide similar compatibility and strength. The attachment 30 elements come in various lengths and diameters to accommodate the size of the prosthesis, which may vary due to the variation of human anatomy.

The foregoing describes the system and how its components are interrelated. An example of a typical installation sequence for the system will now be described.

35 The approach to the surgery can be either the standard anterior transabdominal or retroperitoneal approach. The first step in the sequence is resection of the disk so that the resection is 1.5 inches wide and 1.5 inches deep. There must be as much of the anterior longitudinal ligament left as possible on either side of the disectomy. The next step is to denude the adjacent surfaces to bleeding bone, and then distract the disk space with a distracter chosen by the surgeon

or with a triple arthodesis distracter. After those steps are complete, obtain an anterior-posterior and lateral x-ray to determine that the motion segment is distracted to a reasonable height and
5 still in alignment. Then, measure the distraction, which should ideally be about 18 mm, and assemble and insert the prosthesis. After the prosthesis is inserted, insert the cancellous screws through the flanges in the prosthesis to the vertebral bodies about and below. Take final x-rays, and close in a routine manner.

10 The preceding description indicates the preferred embodiments of the present invention, but it is not limited to the designs shown. Therefore, the present invention is not intended to be limited to the working embodiments described above. The scope of the invention is defined in the following claims.

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WHAT IS CLAIMED IS:

5 1. An intervertebral prosthetic disk comprising:
 a) a male component comprising a first support plate, a first attachment element allowing fixation to a vertebra, and an articulating projection;
 b) a female component comprising a second support plate, a second attachment element allowing fixation to a vertebra, and a circular pocket with angled walls suitable for receiving the articulating projection.

10 2. The prosthetic disk of claim 1, wherein the first and second attachment elements each comprise at least one vertical flange extending from the support plate and contain at least one opening through which a mechanical attachment element can pass.

15 3. The prosthetic disk of claim 2, wherein the mechanical attachment element comes from the group consisting of screws, pegs and rods.

20 4. The prosthetic disk of claim 3 wherein the number of openings and mechanical attachment elements is at least two on both the male and female components.

25 5. The prosthetic disk of claim 1, wherein the first and second attachment elements are a porous coating for permanent bony fixation on a bone-facing surface of the support plates.

30 6. The prosthetic disk of claim 1, wherein the first and second attachment elements each comprise at least one flange, at least one mechanical attachment element, and a porous coating on a bone-facing surface of the support plates.

35 7. The prosthetic disk in claim 1, wherein the first support plate is wedge-shaped to facilitate building lordosis.

40 8. The prosthetic disk of claim 1, wherein at least one of the components is made of a material selected from the group consisting of ceramics and metal alloys.

45 9. The prosthetic disk of claim 1, wherein both of the components are made of a metal alloy.

50 10. The prosthetic disk of claim 9, where the metal alloy is chromium cobalt.

11. The prosthetic disk of claim 1, wherein the articulating projection is doughnut shaped to facilitate range of motion.

5

12. The prosthetic disk of claim 1 wherein the angled walls of the circular pocket allows the male component to self-center within the female component.

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13. The prosthetic disk of claim 7 wherein the wedge shaped plate comprises a recessed, angled hole through which an attachment element can pass.

14. The prosthetic disk of claim 13 wherein the attachment element is a screw.

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15. The prosthetic disk of claim 1 wherein the second support plate comprises a recessed, angled hole through which an attachment element can pass.

20

16. The prosthetic disk of claim 15 wherein the attachment element is a screw.

17. The prosthetic disk of claim 2 wherein the flange includes at least one opening selected from the group consisting of circular, oval, and figure-eight patterns.

25

18. The disk recited in claim 1 wherein the articulating projection, when inside the circular pocket, provides multiple centers of rotation for flexion, extension, and lateral flexion and rotation.

25

19. The disk recited in claim 1 wherein the mechanism allows for at least approximately 15 degrees of flexion, 5 degrees of extension, 1 degree of rotation and 5 degrees of lateral bending.

30

20. An intervertebral prosthetic disk comprising:

a) a male component comprising an articulating projection with a double radius; and

b) a female component comprising a pocket which can receive the articulating projection of the male component.

35

21. An intervertebral prosthetic disk recited in claim 20 wherein a coating or insert is provided on the inside surface of the pocket.

22. The intervertebral prosthetic disk recited in claim 21 wherein the coating or insert is either plastic or ceramic.

5

23. An intervertebral prosthetic disk comprising:

a) a male component comprising a first means for supporting, a first means for attaching allowing fixation to a vertebra, and an articulating projection;

10

b) a female component comprising a second means for supporting, a second means for attaching allowing fixation to a vertebra, and a circular pocket with angled walls suitable for receiving the articulating projection.

15

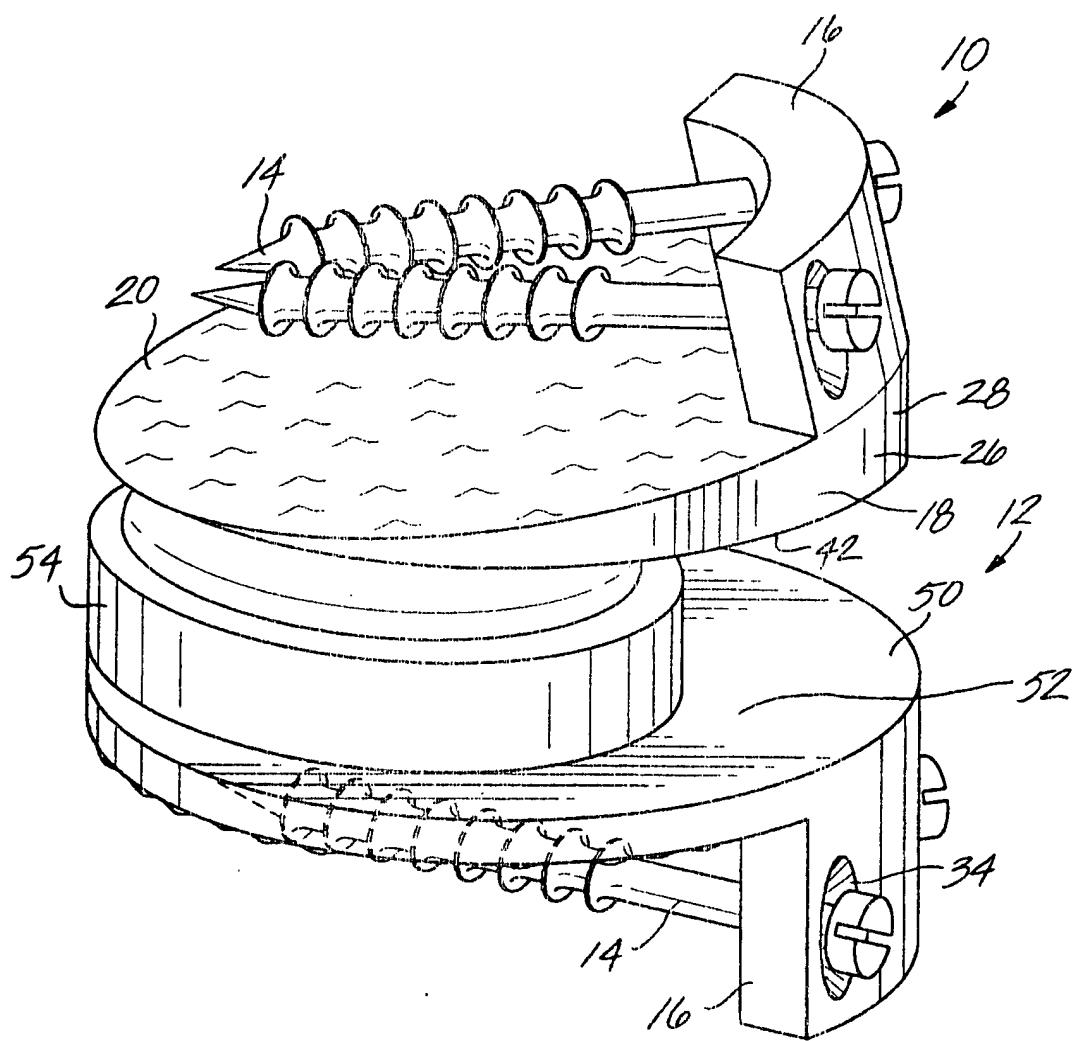
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FIG. 1



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FIG. 2

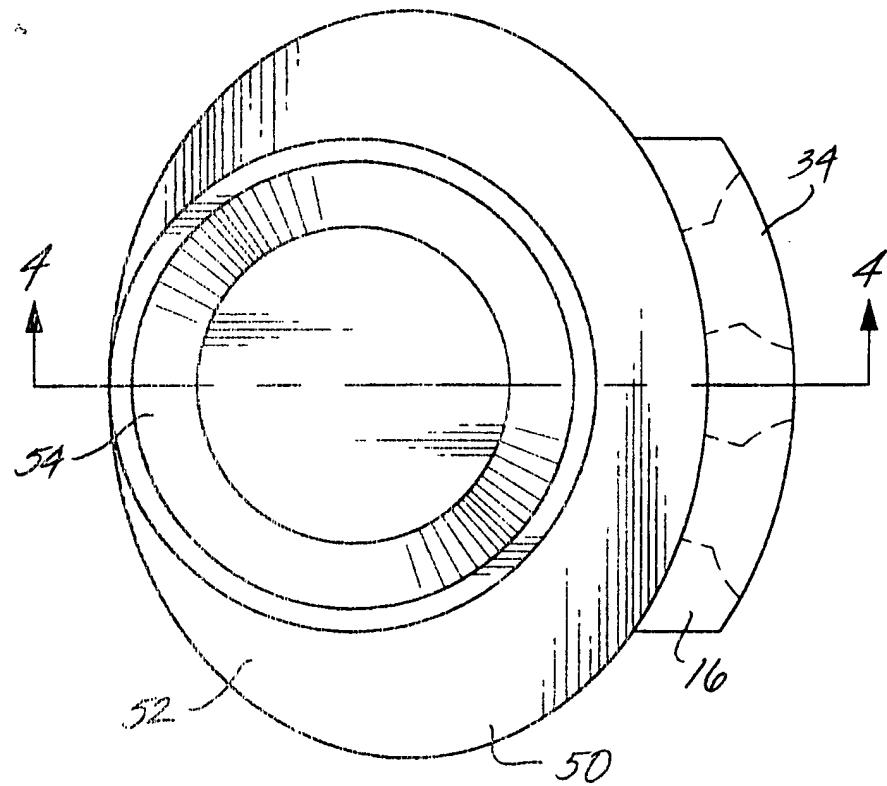
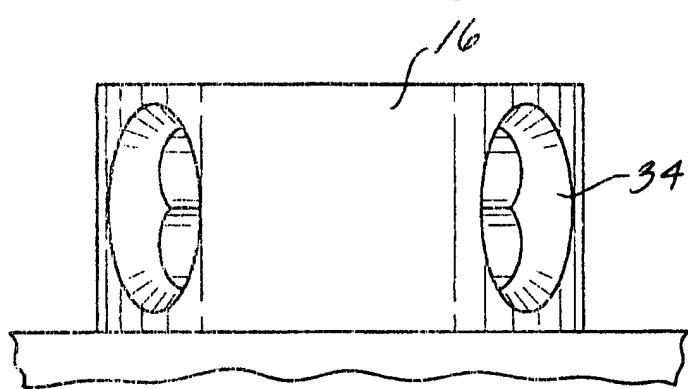


FIG. 3



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FIG. 4

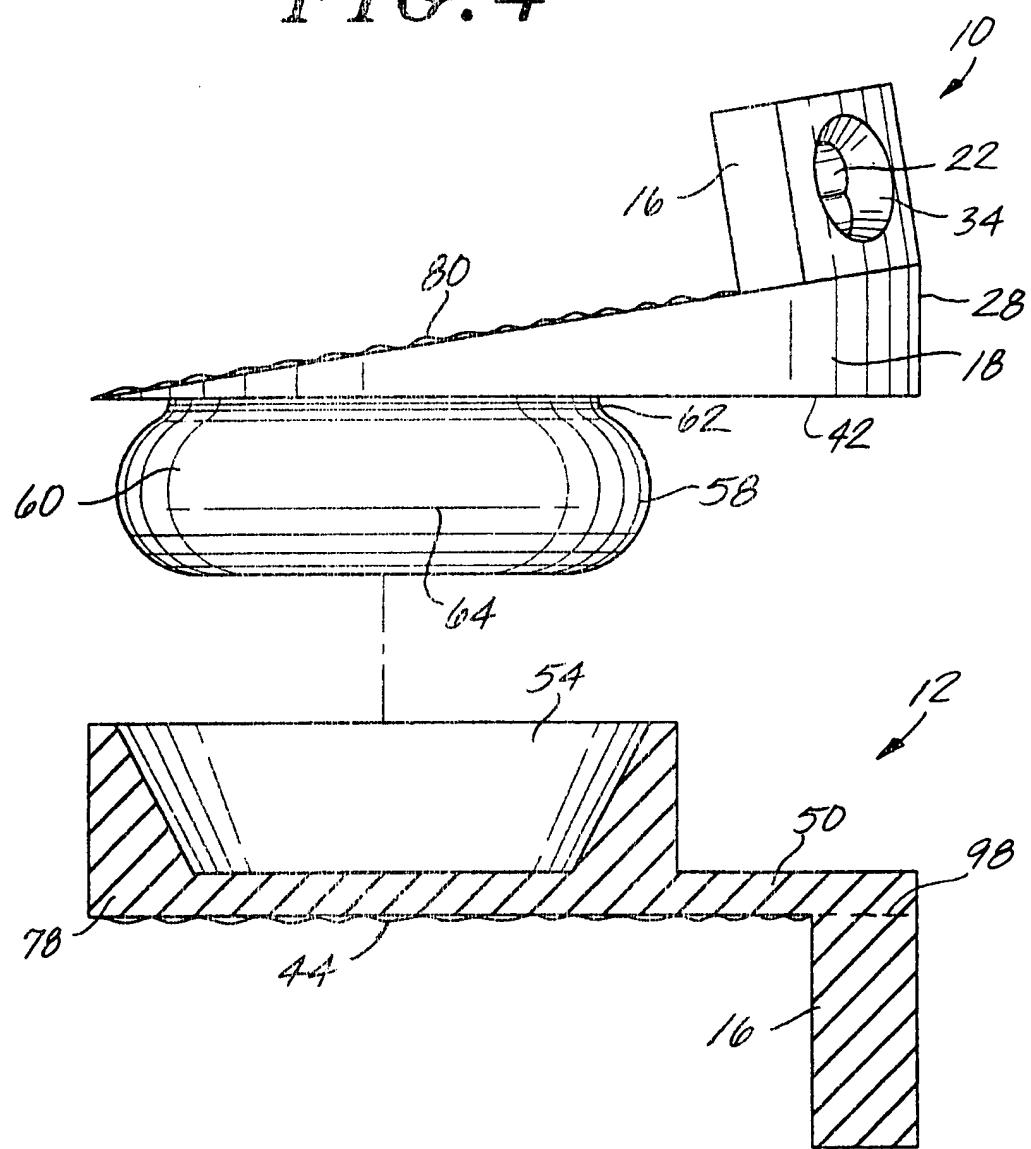
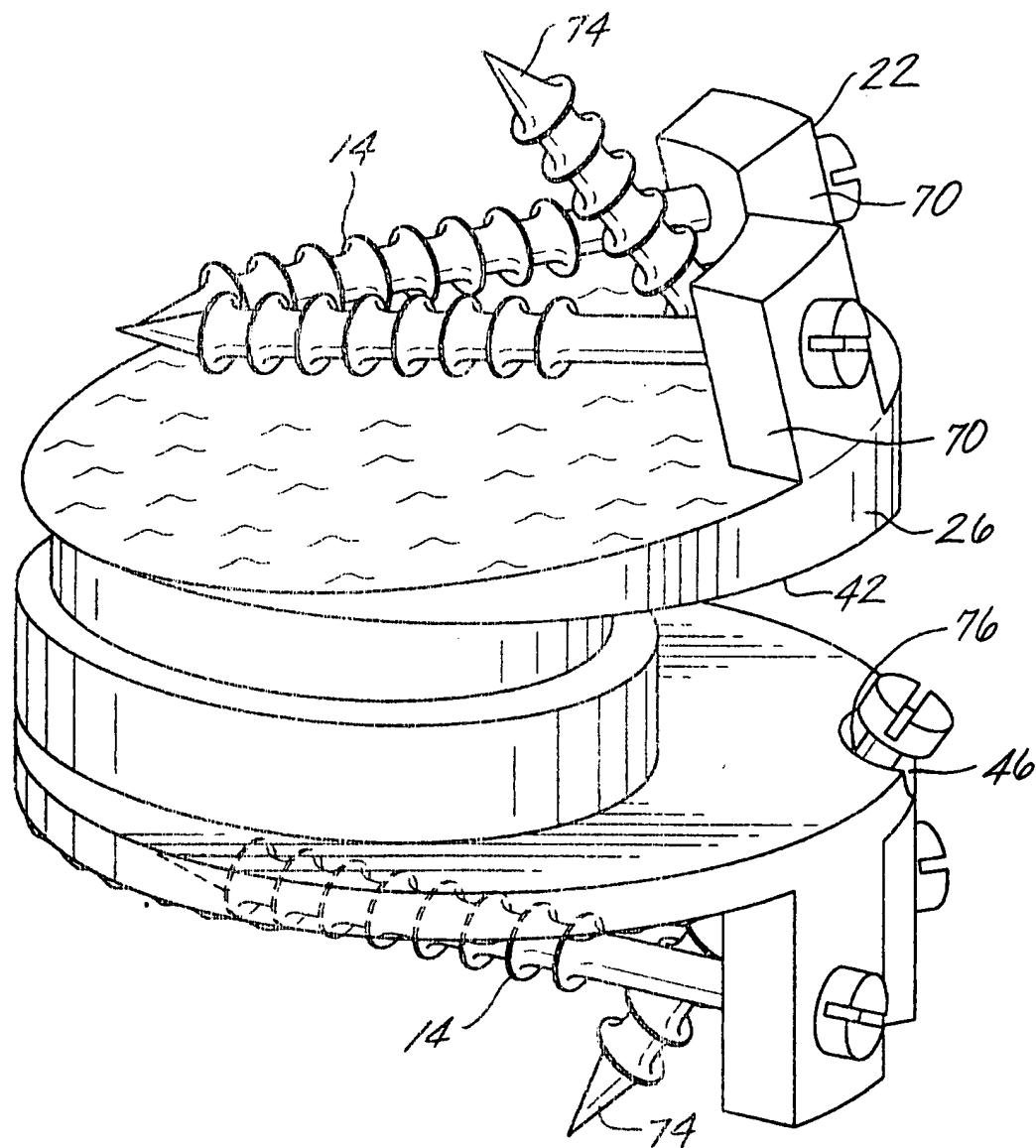


FIG. 5



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/16250

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/44

US CL :623/17

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category ^a	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,360,430 A (LINV) 01 November 1994, figures.	1-3, 8-10, 12, 17, 19, 20, 23

Y		4-7, 13-16, 21, 22
X	US 5,562,738 A (BOYD et al.) 08 October 1996, entire document.	1-3, 5-10, 12, 17-20, 23

Y		4, 13-16, 21, 22

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Authorized official

DAVE WILLSE

Telephone No. (703) 303-2903